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Report Highlights:

Paraguay is the fourth largest soybean exporter in the world, producing about two percent of world soybean production. In 2004 four RR soybean varieties were approved and in March 2005, a royalty payment agreement was reached for the use of GMO soybeans for the 2004/2005-crop year and beyond. Additionally, due to the losses of soybean seed production caused by last year's drought, unregistered RR soybean varieties are temporarily allowed to be imported and sown.

Includes PSD Changes: No
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Executive Summary

Paraguay is the fourth largest soybean exporter in the world, producing about two percent of the world soybean production. About 70 percent of all soybeans sown in Paraguay are Round Up Ready (RR, glyphosate resistant). Up until the last crop season, the country did not allow imports of GMO seeds. However, Paraguayan farmers agreed this past March to pay royalties to Monsanto for the use of its GMO soybeans for the 2004/2005-crop year. This means that Paraguay has opened its doors to the legal entry of environmentally adapted seeds, which will significantly boost soybean-growing activities.

Paraguay has still not passed a biosafety law. In November 2002, a draft biosafety bill was sent to the Paraguayan National Congress that would regulate the eventual production and commercial release of GMO products in Paraguay. The Ministry of Agriculture drafted the bill in conjunction with FAO, and with input from interested sectors of Paraguayan society. The Ministries of Agriculture, Environment and Health would jointly enforce the law, while the Biosecurity Commission, which was created in 1997, would continue to advise the Ministries on technical issues. The recently created National Service of Seed and Vegetables Quality (SENAVE) would advise the Ministry of Agriculture on policy issues.

In 2003, Paraguay ratified the Cartagena Protocol on Biosafety (CBP). The Secretariat of Environment is seeking Paraguayan Central Government consent to administer the provisions of the CBP. This request has met with resistance from other ministries, as there is concern that the Environment Secretariat does not have the technical expertise required to understand the implications of the CBP.

Production and Trade

Paraguay approved in October 2004 four soybean varieties containing the Roundup Ready genes (RR), for planting and marketing. About 70 percent, or 1,5 million hectares, is planted with RR varieties. At the moment there are ten RR varieties approved for planting and commercialization. (Appendix A)

There are under analysis two Maize varieties, MON 810 and NK 603 (both Monsanto varieties) that are expected to be in the market the next crop season.

Paraguay imports biotech seeds from Argentina (nearly 80 %) and from Brazil.

Approvals from Argentina, the United States, and Canada are taken into account as a precedent in the approval evaluation process.

Policy

Current Situation of Regulatory Framework

The current regulatory framework applied to GMOs and to biosecurity is incomplete, unclear, and without a legal framework. Paraguay, in recognition of its need to regulate GMOs, proposed a biosecurity law based on: discussions within the biosecurity commission, regulations in place in MERCOSUR countries and the results of three public hearings. The Paraguayan Congress has been evaluating this proposal since April 2003

At present, relevant laws or regulations in force regulate approval for experimentation and commercialization with GMOs. Current laws and/or regulations are related to compliance

with international laws, such as article 19 of the Cartagena Protocol, and national laws and regulations that protect the environment, biodiversity, and human health. In 1997, under Decree 18481, the Biosecurity Commission was created, with the objective of analyzing and advising on the introduction, field trials, and environmental release of GMO plants. This commission acts as an advisory organism and includes representatives of the Ministry of Health, the Ministry of Agriculture and Livestock and the Ministry of Environment, as well as representatives of scientific institutions and representatives of the production sector. Functions of this commission include the receipt and evaluation of requests for use of GMOs and risk analysis, (a private company selected by public competition will carry out this analysis). Additionally, as requested by the involved ministries, the Commission will cooperate with the functions of control and inspection and will be responsible for information exchange with national and/or international public and private institutions in reference to risk analysis and approval for commercialization of GMOs. Finally, the Commission will provide technical advice to the involved ministries in reference to policy implementation and national strategy related to biosecurity.

Creation of SENAVE

In October 2004, under Decree 5042 a new organism was created, the National Service of Seed and Vegetables Quality, SENAVE (Servicio Nacional de Calidad y Sanidad Vegetal, in Spanish), as a fusion of the National Seed Direction, the National Direction of Vegetal Defense, the National Control Office for Tobacco and Cotton and the Office in charge of domestic and international commercialization of vegetable sub products of the Ministry of Agriculture.

In general terms, the functions of SENAVE are:

- To preserve the introduction of exotic diseases in the country.
- To take the lead in issues related to biotechnology.
- To be the application authority of all in force laws related to seed and cultivars protection.
- To be application authority of international agreements related to seed quality and safety and to protection to vegetal biotech species.
- To advise the Minister of Agriculture in formulation and continuation of a national policy related to production of seed and products derived of biotechnology.

It is still unclear how the SENAVE will interact with the other organisms involved in the approval and regulation of GMOs.

Resolution N. 020 (Appendix A)

On June 2005, SENAVE's President launched a resolution authorizing that varieties that are still pending inclusion in the government seed registry, may be imported and commercialized this crop season (2005/2006) paving the way for several companies that had started but not finished with the approval process yet.

This measure was taken due to a prolonged drought that affected the country that severely impacted the quality and quantity of seed production. After a report of the National Seed Direction informing that the availability of seed for this season would only cover 25 percent of the demand, the Ministry of Agriculture took a non precedent action by approving through resolution the import of GMO seed varieties (RR soybeans) for the campaign 2005/2006 that have not been yet approved for commercialization.

This measure aroused diverse reactions from different sectors, while several agricultural associations applauded the government stating that the measure would legalize the

inevitable entrance of black market seed from neighboring countries, others strongly criticized SENAVE claiming that the measure is illegal and a violation to the country's Seed Law.

Traceability

No provision for a traceability system is in place nor has been included under the proposed law. Tests for GMO content on shipments arriving in Paraguay are not contemplated either.

Labeling

GMO products that are marketed will bear a label, which will contain specific information required by the Ministry of Industry and Commerce. It should be noted that officials of the Ministry of Agriculture, when questioned about labeling requirements, responded that Paraguay would establish information requirements for labeling according to CODEX resolutions. However, this is not stated in the proposed law, where provisions for labeling are vague and unclear.

Stacked Genes

No policy yet.

Coexistence

No policy yet.

Royalties

Framework Agreement signed in support of Royalty Collection System

Farmers in Paraguay agreed on March 2nd 2005 to pay royalties to Monsanto Co. for its genetically modified soybeans in the 2004/2005-crop year.

Paraguayan farmers, as well as those in Brazil and Argentina, have used Roundup Ready soybean seeds for years without paying royalties. In Paraguay they will now pay \$3.22 per bag of seed use to sow one hectare.

The agreement signed between Paraguayan farm lobby groups and Monsanto's Paraguayan branch, and a portion of those royalties will go to crop research and germoplasm improvement within the country.

The system used to reimburse inventors for their technology is similar in structure to the grain-based program implemented in southern Brazil this year. A commission that included members of grower associations, grain handlers, technology providers, and seed companies designed this system.

As part of its commitment to Paraguayan agriculture, Monsanto plans to fund research and development projects, agreed to by the government and agricultural providers that analyze different technologies and germoplasm across a range of growing regions throughout the country.

This new royalties collection scheme is a positive step in closing Latin America's biotech black market. It will be based on grain production and fees will be collected at grain delivery

points. A portion of the fees collected will go to crop research and germoplasm improvement in Paraguay.

Marketing

Since Brazil is the main destination for Paraguayan soybeans, Paraguay's approval policy for GMOs is closely linked to Brazilian policy, which is not defined yet.

Additionally, it is important to mention that the Paraguayan public is not well educated on the topic of agricultural biotechnology. Limited knowledge of popular science among consumers has led to many myths and rumors regarding agricultural biotechnology. The situation of misinformation is even worse in rural areas, where the Church puts some pressure on small farmers against the adoption of new biotech technologies.

There are no relevant studies on marketing of biotechnology products in Paraguay.

Capacity Building and Outreach

2002

- A. FAS Buenos Aires organized a Biotechnology seminar in Paraguay that was very successful in term of attendance (over 400 participants)
- B. Through Cochran Funds, FAS Buenos Aires sponsored a two-week biotechnology training in the United States for 2 Paraguayan government officials, organized in concert by ICD and Michigan State University

2004

- A. FAS Buenos Aires selected one Paraguayan journalist to participate in a U.S. Grains Council activity in Hawaii, where he learned about biotech advances in the papaya industry.
- B. Through Cochran funds, FAS Buenos Aires sponsored a two-week biotechnology training in the United States for one representative of the Paraguayan government, organized by ICD and Michigan State University.
- C. FAS Buenos Aires selected two Paraguayan producers that attended the Farmer-to-Farmer workshop at the University of Zamorano, Honduras.
- D. FAS Buenos Aires organized a two-day conference directed to Congressmen, but also to Media, Academia, Government officials and public in general as a continuation of the seminar organized in 2002. The activity was very successful in terms of attendance (48 congressmen attended the first day and 300 people attended the second day)

2005

- A. FAS Buenos Aires, in concert with FAS Santiago and ICD, organized and accompanied a Southern Cone CODEL to the United States, to demonstrate how the United States uses and regulates agricultural biotechnology. One Paraguayan member of Congress (Deputy) participated in the activity.

Proposed activities

FAS Buenos Aires proposes a continuation of education and outreach activities as well as a more targeted information campaign. Specific activities may include:

- A. Workshops in different cities to target producers and consumers around the country, in areas that rarely have access to "first hand" information.
- B. Coordination with local universities to demonstrate the benefits of biotechnology in Paraguay.
- C. Continue Cooperator, Cochran and International Visitor Program activities
- D. Conduct special activities designed for Consumer Association leaders and consumers in general.
- E. Workshop especially directed to medical doctors and nutritionists, explaining the innocuousness of biotech products
- F. New strategies to better educate small farmers to understand this technology, along with more frequent, sustained efforts to do so.
- G. Conduct a regional workshop in risk assessment directed to Argentine, Paraguayan, and Uruguayan experts.

Appendix A

Crop	Trait Category	Event/ Applicant	Trait Description	Status
Soybean	Herbicide Tolerant	M-SOY 7878 Monsanto	Glyphosate Herbicide Tolerant	Approved Feed and/or Food
Soybean	Herbicide Tolerant	M-SOY 8080 Monsanto	Glyphosate Herbicide Tolerant	Approved Feed and/or Food
Soybean	Herbicide Tolerant	AW 5581 Monsanto	Glyphosate Herbicide Tolerant	Approved Feed and/or Food
Soybean	Herbicide Tolerance	AW 7110 Monsanto	Glyphosate Herbicide Tolerant	Approved Feed and/or Food
Soybean	Herbicide Tolerance	A6019RG NIDERA	Glyphosate Herbicide Tolerant	Approved Feed and/or Food
Soybean	Herbicide Tolerance	A 8000RG NIDERA	Glyphosate Herbicide Tolerant	Approved Feed and/or Food
Soybean	Herbicide Tolerance	A 8100RG NIDERA	Glyphosate Herbicide Tolerant	Approved Feed and/or Food
Soybean	Herbicide Tolerance	CD 212RR COODETEC	Glyphosate Herbicide Tolerant	Approved Feed and/or Food
Soybean	Herbicide Tolerance	CD 213RR COODETEC	Glyphosate Herbicide Tolerant	Approved Feed and/or Food
Soybean	Herbicide Tolerance	CD 214RR COODETEC	Glyphosate Herbicide Tolerant	Approved Feed and/or Food
Soybean	Herbicide Tolerance	CD 219RR COODETEC	Glyphosate Herbicide Tolerant	Approved Feed and/or Food
Soybean	Herbicide Tolerance	DALIA 500 AGRISEED SA.	Glyphosate Herbicide Tolerant	Under Evaluation Import Approved under Res. 020
Soybean	Herbicide Tolerance	DM4200 DAIRYLAND SEED CO INC	Glyphosate Herbicide Tolerant	Under Evaluation Import Approved under Res. 020
Soybean	Herbicide Tolerance	DON MARIO 4870 DAIRYLAND SEED	Glyphosate Herbicide Tolerant	Under Evaluation Import Approved

		CO INC		under Res. 020
Soybean	Herbicide Tolerance	DON MARIO 4600 DAIRYLAND SEED CO INC	Glyphosate Herbicide Tolerant	Under Evaluation Import Approved under Res. 020
Soybean	Herbicide Tolerance	A4910RG NIDERA	Glyphosate Herbicide Tolerant	Under Evaluation Import Approved under Res. 020
Soybean	Herbicide Tolerance	A5409RG NIDERA	Glyphosate Herbicide Tolerant	Under Evaluation Import Approved under Res. 020
Soybean	Herbicide Tolerance	A5901RG NIDERA	Glyphosate Herbicide Tolerant	Under Evaluation Import Approved under Res. 020
Soybean	Herbicide Tolerance	A6040RG NIDERA	Glyphosate Herbicide Tolerant	Under Evaluation Import Approved under Res. 020
Soybean	Herbicide Tolerance	A6040RG NIDERA	Glyphosate Herbicide Tolerant	Under Evaluation Import Approved under Res. 020
Soybean	Herbicide Tolerance	NA6126RG NIDERA	Glyphosate Herbicide Tolerant	Under Evaluation Import Approved under Res. 020
Soybean	Herbicide Tolerance	NA6355RG NIDERA	Glyphosate Herbicide Tolerant	Under Evaluation Import Approved under Res. 020
Soybean	Herbicide Tolerance	A6411RG NIDERA	Glyphosate Herbicide Tolerant	Under Evaluation Import

				Approved under Res. 020
Soybean	Herbicide Tolerance	A7053RG NIDERA	Glyphosate Herbicide Tolerant	Under Evaluation Import Approved under Res. 020
Soybean	Herbicide Tolerance	A 7118RG NIDERA	Glyphosate Herbicide Tolerant	Under Evaluation Import Approved under Res. 020
Soybean	Herbicide Tolerance	A7321RG NIDERA	Glyphosate Herbicide Tolerant	Under Evaluation Import Approved under Res. 020
Soybean	Herbicide Tolerance	A7322RG NIDERA	Glyphosate Herbicide Tolerant	Under Evaluation Import Approved under Res. 020
Soybean	Herbicide Tolerance	A7636RG NIDERA	Glyphosate Herbicide Tolerant	Under Evaluation Import Approved under Res. 020
Soybean	Herbicide Tolerance	NA7708RG NIDERA	Glyphosate Herbicide Tolerant	Under Evaluation Import Approved under Res. 020
Soybean	Herbicide Tolerance	NA8010RG NIDERA	Glyphosate Herbicide Tolerant	Under Evaluation Import Approved under Res. 020
Soybean	Herbicide Tolerance	NA8164RG NIDERA	Glyphosate Herbicide Tolerant	Under Evaluation Import Approved under Res. 020
Soybean	Herbicide Tolerance	NA8413RG NIDERA	Glyphosate Herbicide Tolerant	Under Evaluation

				Import Approved under Res. 020
Soybean	Herbicide Tolerance	A9000RG NIDERA	Glyphosate Herbicide Tolerant	Under Evaluation Import Approved under Res. 020
Soybean	Herbicide Tolerance	ADM 4800 CALLAHAM ENTERPRISES	Glyphosate Herbicide Tolerant	Under Evaluation Import Approved under Res. 020
Soybean	Herbicide Tolerance	ADM 50048 CALLAHAM ENTERPRISES	Glyphosate Herbicide Tolerant	Under Evaluation Import Approved under Res. 020
Soybean	Herbicide Tolerance	DM6200 ASOCIADOS DON MARIO	Glyphosate Herbicide Tolerant	Under Evaluation Import Approved under Res. 020
Soybean	Herbicide Tolerance	DM5800 ASOCIADOS DON MARIO	Glyphosate Herbicide Tolerant	Under Evaluation Import Approved under Res. 020
Soybean	Herbicide Tolerance	DM5.8i ASOCIADOS DON MARIO	Glyphosate Herbicide Tolerant	Under Evaluation Import Approved under Res. 020
Soybean	Herbicide Tolerance	DM5.2i ASOCIADOS DON MARIO	Glyphosate Herbicide Tolerant	Under Evaluation Import Approved under Res. 020
Soybean	Herbicide Tolerance	Anta 83 RELMO	Glyphosate Herbicide Tolerant	Under Evaluation Import Approved under Res. 020
Soybean	Herbicide	NM70R	Glyphosate	Under

	Tolerance	RELMO	Herbicide Tolerant	Evaluation Import Approved under Res. 020
Soybean	Herbicide Tolerance	MARIA 500 RELMO	Glyphosate Herbicide Tolerant	Under Evaluation Import Approved under Res. 020
Soybean	Herbicide Tolerance	NA66R RELMO	Glyphosate Herbicide Tolerant	Under Evaluation Import Approved under Res. 020
Soybean	Herbicide Tolerance	N49R RELMO	Glyphosate Herbicide Tolerant	Under Evaluation Import Approved under Res. 020
Soybean	Herbicide Tolerance	MERCEDES 70 RELMO	Glyphosate Herbicide Tolerant	Under Evaluation Import Approved under Res. 020
Soybean	Herbicide Tolerance	RAFAELA58 RELMO	Glyphosate Herbicide Tolerant	Under Evaluation Import Approved under Res. 020
Soybean	Herbicide Tolerance	NM55R RELMO	Glyphosate Herbicide Tolerant	Under Evaluation Import Approved under Res. 020
Maize	Herbicide Tolerance	NK 603 Monsanto	Gliphosate Herbicide Tolerant	Research
Maize	Insect Resistant	MON 810 Monsanto	Resistant EuropeanCorn Borer	Research

Appendix B**Resolution N. 020, Authorization for Commercial Use of Soybean varieties in crop season 2005/2006**

On June 13, the president of SENAVE signed Resolution N.020 in response to the request of the National Seed Direction. The factors that motivated the request were the drought that affected the country, the fact that the availability of seed for this season would only cover 25 percent of the demand, and the interest that several producers and seed importers expressed in registering seed varieties not included yet in the National Registry of Commercial Cultivars. The National Seed Direction will monitor the fulfillment of the resolution.

The Resolution authorizes the commercial use of soybean varieties ONLY for the crop season 2005/2006 under the following conditions:

- a. The inscription of the variety in the National Registry of Commercial Cultivars must have been initiated prior to the 2005/06-crop season.
- b. The variety may have one year of agronomic evaluation in the 2005/06-crop season.
- c. The importer/producer is totally responsible for the commercial use of the varieties.
- d. The authorization for commercial use of the variety does not mean that it the variety will be definitely included in the National Registry of Commercial Cultivars for use in future crop seasons (it is a temporary permit for this year only).

Appendix C

Procedure to get government authorization for activities with GMOs applicable to events developed in Paraguay or to be introduced from another country.

Provide to Biosecurity Commission:

- Full name, citizenship, legal address, contact information of applicant
- Name and identity of the GMO
- Projected use of the GMO.
- Detailed agenda of the activities that will be developed
- Amount or volume of GMO that will be used
- Report of the known and available risk analysis
- Suggested method of manipulation, storage, transportation, packaging, labeling and disposal procedures that may be needed in case of emergency.
- A formal declaration stating that all data provided is accurate.

Once the applicant has complied with this request, the Commission will evaluate the necessity to perform the risk analysis evaluation. The Commission may decide whether there is need for the risk analysis evaluation, taking into account the approval that other countries have given to that GMO under similar conditions.

As soon as the Commission reaches a decision, it will be published for three consecutive days in national newspapers. The information published includes name of GMO, name of applicant and requested use, as well as a summary of the risk analysis. After this, and if the GMO under consideration is approved, the public in general has the opportunity to voice opposition for thirty days. In such a case, the applicant will be contacted and will have 15 days to respond to the opposition. If necessary, the GMO will be placed on a probation for a period that will be decided by the ministries involved, after which the final decision will be made.

Failure to comply with all conditions of a granted authorization may lead to cancellation of the permit, and to legal actions.

All ministries involved in the final decision must be in agreement with the approval.